BIOMET

510(k) Summary K052639

Preparation Date:	April 12, 2006
Applicant/Sponsor:	Biomet Manufacturing Corp.
Contact Person:	Susan Alexander
Proprietary Name:	Generation 4® Polished Femoral Hip System with Proximal Cement Spacer
Common Name:	Prosthesis, Hip, Femoral Component, Cemented, Metal
Classification Name:	The Generation 4® Polished Femoral Hip Prosthesis has the following classification: Class II, 21 CFR §888.3350.

MAY 3 2006

The mating components (modular heads and acetabular shells/liners) for use with the Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer have the following classifications:

1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310), Product Code: KWZ
2. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR§ 888.3350), Product Code: JDI
3. Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR§ 888.3360), Product Code: JDG
4. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353), Product Code: MEH
5. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. §888.3358), Product Code: LPH
6. Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR §888.3370), Product Code: LZY
7. Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR§888.3390), Product Code: KWY
8. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353), Product Code: LZO

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

- Generation 4® Polished Femoral Hip Prosthesis – Biomet Manufacturing Corp. (K031734)
- Rx-90™ Femoral Stems and Lateralized Stems – Biomet Manufacturing Corp. (K023085)
- Rx-90™ Femoral Component – Biomet, Inc. (K942028)

Device Description:

The Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer is designed to replace the patient's natural hip femoral neck and head damaged due to disease or accident. The femoral hip prosthesis is made from forged Co-Cr-Mo per ASTM F799, and the proximal cement spacers are made from polymethylmethacrylate (PMMA). The implants are designed for use with bone cement. General implant surfaces are highly polished. In addition to the proximal cement spacer, an optional distal cement centralizer (cleared in K942479) is available for optimum stem placement within the canal.

Indications

The indications for use for the Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid Arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

The Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer is intended for cemented use only and may be used in partial and total hip arthroplasties.

Summary of Technologies:

The Generation 4® Polished Femoral Hip System is manufactured from the same materials, utilizing the same manufacturing practices, and conforming to the same standards as other femoral hip prostheses cleared for cemented use.

Non-Clinical Testing:	Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.
Clinical Testing:	No clinical testing was necessary for determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Biomet Manufacturing Corp.
% Ms. Susan Alexander
Regulatory Specialist
P. O. Box 587
Warsaw, Indiana 46581-0587

Re: K052639
Trade/Device Name: Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, LZO, KWZ, MEH, LPH, KWY, JDG
Dated: April 12, 2006
Received: April 13, 2006

Dear Ms. Alexander:

This letter corrects our substantially equivalent letter of May 3, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucchi for MNM

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052639

Device Name: Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer

The indications for use for the Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid Arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

The Generation 4® Polished Femoral Hip Prosthesis with Proximal Cement Spacer is intended for cemented use only and may be used in partial and total hip arthroplasties.

Prescription Use ___X___ AND/OR Over-The-Counter Use__NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052639